

REMARKS

The applicants have studied the Office Action dated December 27, 2007, and have made amendments to the application. It is submitted that the application, as amended, is in condition for allowance. By virtue of this amendment, claims 1, 3-16, and 18-30 are pending and claims 1 and 16 have been amended. Reconsideration and allowance of all of the claims in view of the above amendments and the following remarks are respectfully requested.

Claims 1-2, 9-17, and 24-30 were rejected under 35 U.S.C. § 102(b) as being anticipated by: (1) U.S. Patent No. 4,435,173 to Siposs et al; (2) U.S. Patent No. 5,709,654 to Klatz et al; and (3) U.S. Patent No. 5,151,093 to Theeuwes et al. These rejections are respectfully traversed.

In the Final Office Action, the Examiner has again argued that the cited 102(b) references disclose each and every element of the claimed subject matter. However, the Examiner has not shown where each reference discloses, teaches or suggests an external infusion device having at least one vent port covered with a hydrophobic material that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port covered with the hydrophobic material, as recited in the amended claims. Specifically, independent claims 1 and 16 recite—“[a]n external infusion device for infusion of a fluid into a body from a reservoir, the external infusion device comprising: a drive system . . . ; a housing . . . ; electronic control circuitry . . . ; wherein the housing has at least one vent port covered with a hydrophobic material that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port covered with the hydrophobic material” (emphasis added).

In the Final Office Action at page 5, the Examiner disagreed with the arguments made in the previous response and argues that the “*references disclose medical devices which are made of either plastic or metal which are both hydrophobic materials.*” Applicants urge the Examiner to reconsider his arguments in view of the explanation as follows and as described in the specification.

The present application's disclosure explains, in detail, the advantages of including a vent port covered with a hydrophobic material in an external infusion device (see, for example, paragraphs [0082]-[0087] and accompanying figures):

[0082] As previously noted, the construction of these pumps to be water resistant can give rise to operational problems. As the user engages in activities which expose the pump to varying atmospheric pressures, differential pressures can arise between the interior of the air tight/water-resistant housing and the atmosphere. Should the pressure in the housing exceed external atmospheric pressure, the resulting forces could cause the reservoir piston to be driven inward thus delivering unwanted medication. On the other hand, should the external atmospheric pressure exceed the pressure in the housing, then the pump motor will have to work harder to advance the reservoir piston.

[0083] To address this problem, a venting port is provided which resists the intrusion of moisture. Referring to FIG. 7b, venting is accomplished through the housing 401 into the reservoir cavity 601 via a vent port 605. The vent port can be enclosed by a relief valve (not shown) or covered with hydrophobic material. Hydrophobic material permits air to pass through the material while resisting the passage of water or other liquids from doing so, thus permitting water resistant venting. One embodiment uses a hydrophobic material such as Gore-Tex®, PTFE, HDPE, UHMW polymers from sources such as W. I. Gore & Associates, Flagstaff, Ariz., Porex Technologies, Fairburn, Ga., or DeWAL Industries, Saunderstown, R.I. It is appreciated that other hydrophobic materials may be used as well.

As explained in the portions of the specification above, pressure equalization is one of the primary concerns addressed by utilizing a vent port covered with a hydrophobic material. By citing specific examples of hydrophobic materials, applicants have explained that general metals and plastics cannot address the pressure concerns. More specifically, the diffusion of air through metal and/or plastic is very low. However, by utilizing a hydrophobic membrane—i.e., Gore-Tex®—air can easily pass through at a better rate than general metals and plastics.

The functional purpose of utilizing a vent port covered with a hydrophobic material is to allow for air pressure equalization without the passage of fluid. As described in the passages above, air pressure equalization is important to ensure the proper function of the external infusion device. If differential pressures arise between the interior of the housing and the atmosphere, the resulting forces may cause adverse effects on either the reservoir piston and/or the motor of the external infusion device. Ultimately, the pressure differential might cause

unwanted delivery of fluids or not enough delivery of fluids. However, this concern must also be balanced with the watertight requirements of the external infusion device. Accordingly, air must easily pass through the housing to ensure pressure equalization, but water must be kept out to ensure a water tight seal. In these embodiments of the invention, the solution is found by including a vent port covered with a hydrophobic material to address both concerns. Hydrophobic materials like Gore-Tex® have specific characteristics and ratings that differentiate it from general metals and plastics—ratings that describe the specific air equalization properties and water-phobic nature of the materials. The cited examples of hydrophobic materials in the specification (at paragraph [0083]) include materials that were specifically designed to carry out the necessary water resistant venting.

These concerns are not addressed by the Examiner's assertion that the 102(b) references are "made of plastic and metal which are both hydrophobic materials." And, as noted in M.P.E.P. 2131, to anticipate a claim, a reference must teach every element of a claim. In particular, a claim is anticipated only if each and every element as set forth in the claim is described in a single art reference. The Examiner has not explained where any of the references disclose, teach or suggest an external infusion device having at least one vent port covered with a hydrophobic material that permits the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port covered with the hydrophobic material, as recited in the claims. In his description of each 102(b) reference, the Examiner has not detailed where each reference discloses, teaches or suggests the above emphasized claim limitation. No column and line numbers are given and no figures are referenced to show that the 102(b) references actually teach the specific claim limitations. Furthermore, the Examiner's assertion on page 5 of the Final Action—that all of the 102(b) references disclose medical devices which are made of either plastic or metal—does not satisfy the limitations recited in the claims. A vent port covered with a hydrophobic material which allows the passage of air but also inhibits the passage of fluid is not disclosed, taught or suggested by the references.

Because the 102(b) references cited by the Examiner fail to teach or suggest an external infusion device having at least one vent port covered with a hydrophobic material that permits

the passage of air into and out of the housing and inhibits the passage of liquids into the housing through the at least one vent port covered with the hydrophobic material, as recited in the claims, these references cannot anticipate the claimed invention. For this reason, applicants respectfully request a withdrawal of the rejections under 35 U.S.C. §102(b).

Claims 3-8 and 18-23 were rejected under 35 U.S.C. §103(a) as being unpatentable over Siposs et al., Klatz et al., or Theeuwes et al. This rejection is respectfully traversed.

The dependent claims 3-8 and 18-23 depend from the independent claims which were patentably distinguished from the references as discussed above. Accordingly, claims 3-8 and 18-23 are also distinguished over the references.

For this reason, applicants respectfully request withdrawal of the rejections of claims 3-8 and 18-23 under 35 U.S.C. §103(a).

In view of the foregoing, it is respectfully submitted that the application and all of the claims are in condition for allowance. Examination and consideration of the application, as amended, are requested.

If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is invited to call the undersigned attorney at (818) 576-5003 should the Examiner believe a telephone interview would advance the prosecution of the application.

Respectfully submitted,

Dated: June 30, 2008

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